OCT 1 1 2005

Section II

K052495

Summary of Safety and Effectiveness
(as required by 21 CFR 807.92)

Atrilaze™ Malleable S-2 Disposable Probe

Submitter: MedicalCV, Inc.
9725 South Robert Trail
Inver Grove Heights, MN 55077
USA

Contact: Denny Steger
V.P. RA/QA
Phone: 651 452 3000
Fax: 651 452 4948

Date of Summary: August 23, 2005

Classification Name: Laser Instrument, Surgical Powered

Common Name: Surgical Laser Instrument

Proprietary Atrilaze™ Malleable S-2 Disposable Probe

Description of Device: The Altrilaze Malleable S-2 Disposable Probe is used with the Atrilaze™ Surgical Ablation System which consists of a generator designed for the delivery of 810nm laser light and a hand held fiber optic light delivery device (probe) fitted with a standard SMA 905 connector at the proximal end. The system may be used in conjunction with surgical treatment for hemostasis, incision, ablation, coagulation and vaporization of tissue as required by the clinician.

Statement of Intended Use: The stated intended use of the Atrilaze Malleable S-2 Disposable Probe is the same as the MedicalCV Atrilaze™ Surgical Ablation System. It is indicated for the delivery of 810nm laser light to soft tissue to include cardiac tissue, during surgical procedures. Indications include the incision, excision, dissection, vaporization, ablation or coagulation of soft tissue.

Warning: The Atrilaze Ablation System is not indicated for the treatment of cardiac arrhythmias.

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use. Burns can occur if the laser energy is not correctly applied. These complications may be serious.

Technological Comparison: The Atrilaze Malleable S-2 Disposable Probe is the same as that of the existing Non-Malleable Disposible Probe that was granted market clearance under K040744. The fiber optic delivery system (probe) is coupled to the laser via an SMA 905 connector to deliver laser radiation to the target tissue(s). For purposes of this submission, the Atrilaze Malleable S-2 Disposable Probe was compared to the following predicate device(s):

- MedicalCV, Inc. Non-Malleable Disposable Probe (K040744)
- CardioFocus, Inc. Malleable Surgical Lightstic 180 (K013901)

Testing: Results of biocompatibility testing support statement that the material change from stainless steel to nitinol had no impact on previously gathered test results (K040744). The probe is non-toxic, non-hemolytic, and non-pyrogenic. All biocompatibility testing was conducted under Good Laboratory Practices per 21 CFR Part 58.

Performance testing for the Atrilaze Malleable S-2 Disposable Probe included compliance to manufacturing specifications for Power Output, Tip Pull-Off, Pressure and Flow for the fiber optic light delivery device. Testing demonstrated that the Altrilaze Malleable S-2 Disposable Probe is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1 2005

Denny Steger
Vice President Regulatory Affairs/
Quality Assurance
MedicalCV, Inc.
9725 South Robert Trail
Inver Grove Heights, Minnesota 55077-4424

Re: K052495
Trade/Device Name: Atrilaze™ Malleable Ablation Probe
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 9, 2005
Received: September 12, 2005

Dear Mr. Steger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Barbara Bucheit
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number: K052495

Device Name: Atrilaze™ Malleable Ablation Probe

Indications for Use: The MedicalCV, Inc. Atrilaze™ Surgical Ablation System is indicated for delivery of 810nm laser light to soft tissue to include cardiac tissue during surgical procedures. Indications include the incision, excision, dissection, vaporization, ablation, or coagulation of soft tissue.

Warning: The Atrilaze™ Surgical Ablation System is not indicated for the treatment of cardiac arrhythmias.

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use. Burns can occur if the laser energy is not correctly applied. These complications may be serious.

Prescription Use__X__ OR Over–the-Counter Use____
(Per 21 CFR 801.109)

(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052495